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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/937,687	05/09/2002	Finbarr Paul Mary O'Harte	8830-8	5098

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EXAMINER	
RUSSEL, JEFFREY E	
ART UNIT	**PAPER NUMBER**
1654	

DATE MAILED: 05/28/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/937,687	O'HARTE ET AL.	
	Examiner	Art Unit	
	Jeffrey E. Russel	1654	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *03 May 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-6 and 8-22* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☒ Claim(s) *3,10 and 11* is/are allowed.

6)☒ Claim(s) *1,2,4-6,8,9,12,13 and 17-22* is/are rejected.

7)☒ Claim(s) *14-16* is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *28 September 2001* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☒ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

1. A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on May 3, 2004 has been entered.

2. Claims 1, 2, 4-6, 8, 9, 12, 13, and 17-21 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The phrase "the analogue containing Tyr^1 glucitol GIP(1-42)" at claim 1, lines 2-3, and at claim 13, lines 2-3, is unclear. It is not clear how an analogue which can comprise as few as 15 amino acid residues can also contain a 42-amino acid analogue. It is not clear if Applicants are requiring, e.g., a mixture of two different analogues, or that a Tyr residue be present at position 1 of any analogue. To the extent that claim 4 depends upon claim 20 or claim 22, there is no antecedent basis in the claims for the phrase "the additional amino acid modification at claim 4, line 2. Claims 20 and 22 do not use the term "additional". Claim 4 is indefinite because it recites that the additional modification can be a D-amino acid substitution in position 1 or can be an N-terminal glycation, alkylation, acetylation or acylation. However, claim 1 has been amended to define the additional amino acid substitution or modification as occurring at positions 2 or 3. Accordingly, claim 4 contradicts independent claim 1 as to where the additional substitutions or modifications can take place. Claim 1 appears to distinguish between substitutions and modifications of the amino acids at positions 2-3 (see line 4 of claim 1). However, claim 4 indicates that the modification can be a substitution (compare line 2 with lines 3-4), and thus appears to indicate that modifications and

substitutions are overlapping categories, or that the latter is a species of the former. Claim terminology needs to be standardized, e.g., by amending claim 4, line 2, to read "wherein the additional amino acid substitution or modification is". The use of the word "or" at claim 20, line 3, first occurrence, and at claim 21, line 3, first occurrence, makes it unclear as to whether the claimed analogues are required to have a D-Tyr residue present at position 1, or whether this amino acid substitution is an alternative to the N-terminal alkylations, acetylations, or acylations.

3. Claims 4, 5, and 14-16 are objected to under 37 CFR 1.75(c), as being of improper dependent form for failing to further limit the subject matter of a previous claim. Applicant is required to cancel the claim(s), or amend the claim(s) to place the claim(s) in proper dependent form, or rewrite the claim(s) in independent form. To the extent that claim 1 requires a Tyr residue to be present at position 1 (see also the above rejection under 35 U.S.C. 112, second paragraph, as to the possible interpretations of claim 1), claim 4 does not further limit the claim because it permits the Tyr^1 residue to be substituted by a D-amino acid. To the extent that claim 4 permits a D-amino acid other than D-Tyr to be substituted at position 1, and to the extent that claim 4 permits amino acid substitutions at positions 2 and 3, claim 4 does not further limit claim 20, which does not permit such substitutions. Claim 5, which permits substitution at position 2 or 3 of GIP(1-42), does not further limit claim 20, which does not permit such substitutions. Claims 14-16, which require substitutions or modifications at positions 1-3, do not further limit claim 3, which does not permit such substitutions or modifications.

4. Claim 13 is objected to because of the following informalities: At claim 13, line 3, "Tyr1" should be changed to "Tyr^1". Appropriate correction is required.

5. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

For the purposes of this invention, the level of ordinary skill in the art is deemed to be at least that level of skill demonstrated by the patents in the relevant art. Joy Technologies Inc. v. Quigg, 14 USPQ2d 1432 (DC DC 1990). One of ordinary skill in the art is held accountable not only for specific teachings of references, but also for inferences which those skilled in the art may reasonably be expected to draw. In re Hoeschele, 160 USPQ 809, 811 (CCPA 1969). In addition, one of ordinary skill in the art is motivated by economics to depart from the prior art to reduce costs consistent with desired product properties. In re Clinton, 188 USPQ 365, 367 (CCPA 1976); In re Thompson, 192 USPQ 275, 277 (CCPA 1976).

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 8 and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by the Fujii et al article (Chem. Pharm. Bull., Vol. 34, pages 2397-2410). The Fujii et al article teaches the chemical synthesis of human GIP. Prior to final deprotection of the 42-residue peptide, the tyrosine residue at position 1 is protected, i.e. modified, at N^{α} with Z(OMe) and the glutamic

acid residue at position 3 is protected, i.e. modified, at its sidechain with OChp. The protected 42-residue peptide is isolated as a powder. See Figure 2 and page 2407, fourth and fifth paragraphs. With respect to instant claim 8, an intended use limitation does not impart patentability to product claims which are otherwise anticipated by or obvious over the prior art.

7. Claims 8, 9, and 22 are rejected under 35 U.S.C. 102(b) as being anticipated by the O'Harte et al article (Diabetes, Vol. 48, pages 758-765). The O'Harte et al article teaches administering Tyr^1 glucitol GIP(1-42) intraperitoneally to rats. The GIP analogue causes insulin release and a reduction in plasma glucose levels. See, e.g., the Abstract and page 759, column 2, fourth full paragraph. The Tyr^1 glucitol residue of the O'Harte et al article satisfies the requirement of claim 22 for a substituted or modified amino acid residue at position 1.

8. Claim 12 is rejected under 35 U.S.C. 103(a) as being obvious over the O'Harte et al article (Diabetes, Vol. 48, pages 758-765). Application of the O'Harte et al article is the same as in the above rejection of claims 8, 9, and 22. The O'Harte et al article does not teach treating diabetes using the GIP analog. It would have been obvious to one of ordinary skill in the art at the time Applicants' invention was made to use the GIP analogue of the O'Harte et al article to treat diabetes because the GIP analogue has been demonstrated to have in vivo activities which are useful in treating diabetes, i.e. increasing insulin release and decreasing plasma glucose levels, and because the GIP analogue has the benefit of reduced in vivo proteolysis which would lower needed dosages of the active agent.

9. Applicant's arguments filed May 3, 2004 have been fully considered but they are not persuasive.

Assuming that Applicants intend for claims 1 and 13 to be read as requiring the presence of Tyr[1] glucitol to be present at position 1 of the claimed analogues (see page 7, lines 6 and 9-10 of the response filed May 3, 2004), the anticipation rejection over the Fujii et al article (Chem. Pharm. Bull., Vol. 34, pages 2397-2410) set forth in section 3 of the previous Office action is withdrawn. However, the Fujii et al article is now applied against new claim 22, which does not require that any particular modified residue be present, and against dependent claim 8.

10. Claims 3, 10, and 11 are allowed.

11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Jeffrey E. Russel at telephone number (571) 272-0969. The examiner can normally be reached on Monday-Thursday from 8:30 A.M. to 6:00 P.M. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor Brenda Brumback can be reached at (571) 272-0961. The fax number for formal communications to be entered into the record is (703) 872-9306; for informal communications such as proposed amendments, the fax number (571) 273-0969 can be used. The telephone number for the Technology Center 1600 receptionist is (571) 272-1600.

Jeffrey E. Russel

Primary Patent Examiner

Art Unit 1654

JRussel

May 26, 2004